IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:Gordon, K.
Serial No: 09/932,821
Date Filed: 8/17/2001
Invention: Novel Formulation for administering Therapeutic Lipophilic Molecules Salts

Atty Dkt: 01540/140
Examiner: Bahar, Mojdeh
Group No: 1617
Date: January 7, 2002

CERTIFICATE OF MAILING

I hereby certify that this correspondence addressed to the Commissioner for Patents, Washington, D.C. 20231 is being deposited with the United States Postal Service as first class mail on January 7, 2002.

Harriet M. Strimpel, D. Phil

Commissioner for Patents
Washington, DC 20231

Response A

Dear Sir

In the office action dated December 5, 2001 (Paper 5) in the above identified patent application, Applicants elects as a species the acute medical condition of epileptic seizures.

Moreover, applicants elect Invention IV, claim 1, 5-6 and 22-25.

The restriction request is respectfully traversed on the grounds that the reasoning provided by the Examiner is insufficient to support a finding of four distinct inventions.

Applicants contacted the Supervisory Examiner Minna Moezie to request clarification of this action. Applicants thank the Supervisory Examiner for the opportunity of a telephone conference on December 18, 2001. In the conversation, the Examiner stated that the restriction was actually based on estrogenic and non estrogenic compounds and that a species election should be made with respect to whether the medical condition was acute. This interpretation however was not apparent in Paper 5. Therefore, applicants request written clarification of the restriction request.

The standard for independent claims is that there be "no disclosed relation therebetween" (MPEP ¶808.01). The Examiner states however that "Inventions I and II as well as II and IV are related as product and process of use." In so stating, the Examiner denies that they are independent inventions.

In identifying four classes of claims, the Examiner states that "the process for using the product as claimed can be practiced with another materially different product."

Applicants traverse the restriction into four classes of claims on this basis because the applicants do not claim a product in claim 1. Instead the claimed method requires administering a lipophilic agent with benzyl alcohol subcutaneously to achieve a pharmacokinetic effect suited for treating an acute medical condition. Indeed the use of any composition other than a lipophilic agent would lie outside the claimed invention.

Applicants further traverse the restriction of claims based on Examiner's assertion that a product in claim 1 or independent claims can be used in a materially different process of using that product. In claim 1 and dependent claims, a specific class of compounds have been specified for use in the claimed method only. The patentability of the class of compounds themselves has not been asserted.

Applicants further traverse restriction of claims based on the Examiner's recitation of nitroglycerin. Nitroglycerin is a lipophilic compound and according to the claimed invention is included in the class of compounds for administration subcutaneously with the required pharmacokinetics for treating acute medical conditions.

On page 3 of the action the Examiner has contradicted his earlier statements made on page 2 of the action. On page 3, the Examiner asserts that Invention I and IV are unrelated even though I and IV involve the same claimed invention (claim 1). The Examiner asserts that claim 1 has elements that are not disclosed as capable of use together and they have different modes of operation, different functions or different effects. In particular the Examiner asserts that the different inventions described in claim 1 have different modes of operation.

The restriction is traversed because it is unclear to applicants what the Examiner means by asserting that elements in this claim cannot be used together and why elements have different modes of operation.

On page 3 of the action the Examiner has contradicted statements made on page 2 of the action. On page 3, the Examiner asserts that Invention II and III are unrelated even though II and III involve the same claimed invention. The Examiner asserts that claim 12 has elements that are not disclosed as capable of use together and they have different modes of operation , different functions or different effects. In particular the Examiner asserts that the different inventions described in claim 12 employ different agents.

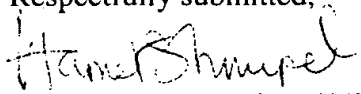
Here the claim states "A dosage unit for subcutaneous administration comprising: a formulation of a non-estrogenic lipophilic molecule in an oil packaged in a dosage unit for subcutaneous delivery".

The restriction is traversed because it is unclear to applicants what the Examiner means by asserting that elements in this claim cannot be used together and why elements have different modes of operation.

In summary, the restriction of the claims into 4 separate inventions is traversed on the grounds that claim 1 and claim 12 should each be considered as a whole. Reasons should be provided with particularity for restricting any of the claims into separate inventions. Should any restrictions be made, the invention groups should at the minimum be capable of separate manufacture, use or sale as claimed and additionally notably, the inventions should be "PATENTABLE (novel and non-obvious) OVER EACH OTHER." (MPEP 802.01)

Examination of the elected claims, and of any other claims deemed, on reconsideration, to be drawn to the same invention, is hereby requested. If the Examiner has any questions in regard to this matter, he is invited to contact Applicants' attorney at the number below. Please charge any additional fee required for the timely consideration of this application to Deposit Account No. 19-4972.

Respectfully submitted,



Harriet M. Strimpel, D.Phil.
Registration No. 37,008
Attorney for Applicant
Bromberg & Sunstein
125 Summer Street
Boston, MA 02110
617/443 9292

January 7, 2002
02430/00105 185220.1